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EXAMINER	
MATTHEWS, WILLIAM H	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
04/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/731,868	SINGHAL ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 24-31* is/are pending in the application.

4a) Of the above claim(s) *13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,15-17 and 24-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-8-08,3-20-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 12-21-07 have been fully considered but they are not persuasive.

Regarding the specification amendment and objection, Applicant argues that the description of Figure 7 is applicable to Figure 8 thus providing support for a pocket in a method shown in Figure 8. Furthermore Applicant contends Figure 8 show "a majority of IMD 12A is located within a pocket". Examiner maintains the specification objection because, regardless of the presence of a pocket in Figure 8, the specification as originally filed lacks a description of a method of placing a majority of the device in a pocket. Figure 8 does not necessarily show a "majority" because Figure 8 may be considered to show half or less than half due to the parts of the device located on the anterior side of the purported pocket. Furthermore, Applicant is relying upon a distinct interpretation of the drawings to find support to include additional subject matter into the specification, but the specification fail to disclose the drawings are to scale. It has been held that drawings do not define precise proportions or sizes if the specification is silent on the issue. In re Wright, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Regarding the 112 1st paragraph rejections:

Applicant's argument regarding the term **"majority"** based on figure 8 is not persuasive for the same reasons described above. In addition, the limitation "a majority" is considered a range that encompasses more than what is shown in Figure 8.

Applicant maintains paragraph [0051] support the combination of steps of forming a pocket and recess and implanting the device in the **recess and pocket** as recited in claims 12 and 27. Examiner disagrees as paragraph [0051] appears to describe an alternative method of implantation and fails to describe the relationship of the pocket and recess and device. Paragraph [0051] fails to disclose formation of a recess and placing the device in the recess in combination with placing a majority of the device in a pocket. Furthermore, Applicant's proposal for the combination method raises several questions about how such a procedure would be carried out. Specifically, a recess would have to be formed underneath a pocket behind the incision, yet the specification fails to disclose or suggest such a step or unique device for fulfilling the step. In addition, if the device is placed in the recess then the device would not be placed in a pocket which is defined as a space between the surface of the skull and scalp.

Applicant maintains paragraph [0022] provides support for implanting the **entire** device in a pocket (claims 25,26,29). Examiner maintains that the statement of paragraph [0022] "The pocket may be opened sufficiently to receive IMD 12 or a portion thereof." fails to clearly suggest all of the device is inserted into the pocket. The term "receive" merely implies IMD can be inserted into the pocket similar to how a lockset receives a key. Examiner has found nowhere else in the written specification or drawings to suggest the entire device may be inserted into the pocket. Applicant requests alternative interpretations of the phrase "IMD 12 or a portion thereof". However, the appropriate phrase to evaluate is the entire sentence as noted above in

combination with the entire paragraph. "The pocket may be opened sufficiently" implies reference is made to the height of the pocket (rather than overall size or volume) necessary to insert IMD or a portion thereof. Furthermore, the final sentence of paragraph [0022] states the flap is drawn "over the portion of IMD 12 **not inside** the pocket 30" (**emphasis** added). Even further, the specification describes "placing or inserting IMD into a pocket" repeatedly when Applicant's intention is actually "a portion" of IMD is inserted into a pocket. For example, in paragraph [0022], the sentence immediately following the passage which Applicant relies upon for support, states: "as shown in FIG. 5, the surgeon inserts low-profile IMD 12 into pocket 30" yet Figure 5 only show a portion of IMD placed in the pocket. Thus the description when read in full context fails to support Applicant's position, and Applicant's characterization of "to receive IMD 12 or a portion thereof" is improper.

Regarding the rejections under 35 USC 102 and 103:

With regard to claim 1, Applicant continues to argue that the "fold" of the Berrang references are located on the right side of the implanted device (as seen when looking at figure 3 of each Berrag reference). Examiner disagrees because the incision has a "start point" and "end point" and a line may be drawn between these points is where the claimed "fold" would be present. The portion of scalp to the left of this "fold" constitutes the "scalp flap" as claimed. To achieve what is shown in each figure 3 of Berrang, this "scalp flap" is separated from the skull first, which inherently would possess a fold where the scalp is still contacting the skull, then the pocket is formed as the scalp portion to the right of the "fold" is separated from the skull. Thereafter a majority of the

device is placed in the pocket. Applicant appears to argue Berrang is different because Applicant's fold must be in contact with the skull. However, the contact between the fold and skull is eliminated upon formation of a pocket.

Regarding claims 25-27, Examiner relies on the reasoning provided above to show each Berrang referece disclose "all of" the device in the pocket.

Regarding claims 11, Examiner maintains the position set forth in the Office action mailed 9-24-07.

Regarding claims 24,28-29 Applicant states it is unclear how aesthetics would be improved by the proposed modification and that it would be impractical because of longer wires necessary to connect the devices. Examiner disagrees because as shown in figure 3 of Berrang, the device is situated directly behind the ear which is a location generally hairless and visible even when wearing a hat. Furthermore, the requirement of longer wires to connect the components does not appear highly impractical compared to excavating the skull of the patient.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12,15-17,24-27, and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "majority", claims 12 and 27 each recite a new combination of placing a device in a pocket and a recess, claims 25,26,29 each recite "placing all of". Claim 27 recites placing all of a device in a recess. These limitations were not described in the specification or drawings as originally filed.

Specification

The amendment filed 9-7-07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "a majority of IMD 12A is located within a pocket behind the scalp flap" as added to paragraph [0036].

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3,5-10,12,15-17,25-27, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. US PN 6,648,914.

Berrang et al. discloses in figures 1-3 and line 42 of col. 9 through line 25 of col. 14 a method of implanting an implantable medical device using local anesthetic comprising creating a pocket (adjacent to a fold) and recess (lines 1-18 of column 10) in the scalp for the implant which comprises a periphery having an angle of approximately 135 degrees, leads, bone screw anchors, first and second module within housings partially covered by a flexible overmold, wherein the maximum thickness is between 4-8mm. Lines 52-59 of col. 14 describe drilling a hole for a lead. Figure 3 show an C-shaped incision and a pocket created right of the C-shaped incision, and adjacent a fold (located along the S-shaped incision), in which all of the implant (as best understood by Applicant's specification) is placed into.

Claims 1-4,7,15,25-27, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. US PUB2003/0109903.

Berrang et al. discloses in figures 1, 3 and 25 and paragraphs 46-48,54-56, and 80 a method of implanting an implantable medical device comprising creating a pocket in the scalp for the implant which comprises leads, first and second module within housings partially covered by a flexible overmold, wherein the maximum thickness is approximately 6mm.

Figure 3 show an C-shaped incision and a pocket created right of the C-shaped incision, and adjacent a fold (located along the C-shaped incision), in which all of the implant (as best understood by Applicant's specification) is placed into.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. US PN 6,648,914 or Berrang et al. US PUB 2003/0109903.

Each of Berrang et al. '914 and '903 independently meet the limitations of claim 11 but lack the express written disclosure of suturing the flap over the implant to complete the implantation procedure. The Examiner hereby takes Official Notice that suturing a skin flap to complete a surgical procedure is well known in the art.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include the step of suturing the flap to close the incision.

Claims 24,28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. US PN 6,648,914 or Berrang et al. US PUB 2003/0109903.

Each of Berrang et al. '914 and '903 independently meet the limitations of claims 24 and 28-29, as described in the 102 rejections above, but each lack the express

written disclosure of implanting the device at the top of the head. Berrang '914 (which is incorporated by reference in '903 at paragraph 0004) disclose the device is preferably located on the head as shown in figure 3 (column 13 lines 35-53), but also describe an unaesthetic visible bump (lines 1-4 of col. 10) of the devices and a desire to improve aesthetics (column 2, lines 36-40). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the placement of the device to a position at the top of the head to eliminate the unaesthetic bump which would be noticeable behind a patient's ear.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. USPN 6427086 in view of Berrang et al. US PN 6,648,914.

Fischell et al. disclose in figure 23 a method of implanting a neurostimulator between the scalp and skull. Fischell et al. lack the express written disclosure of how the device is implanted. Berrang et al. '914 teach in figure a method of implanting a device under the scalp comprising the steps of making an S-shaped incision to create a scalp flap and creating a pocket behind the scalp flap for inserting the device. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Fischell et al. to include the surgical implantation steps of Berrang et al. in order to reduce the incision required to implant the device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3738